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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/009,802 01/20/98 MCCARTHY

S MEI-008-1

HM12/1106  
MILLENNIUM BIOTHERAPEUTICS, INC.  
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EXAMINER

YUCEL, T

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/009,802

Applicant(s)

McCarthy

Examiner

Remy Yucel

Group Art Unit

1636



☒ Responsive to communication(s) filed on Aug 17, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 61-88 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 61-88 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 17

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Claims 61-88 are pending in the application. This Office action is in response to the amendment filed 17 August 2000.

#### ***Response to Amendment***

Claims 61-88 stand rejected under 35 U.S.C. 101 for the reasons made of record in the Office action mailed 13 March 2000.

Claims 61-88 stand rejected under 35 U.S.C. 112, first paragraph for the reasons made of record in the Office action mailed 13 March 2000.

#### ***Response to Arguments***

Applicant traverses the rejections by stating that the specification provides descriptions of the “chemical, physical and biological” properties of the CRSP family of proteins, of which CRSP-2 is a member. In apparent support of this contention, Applicant references specific passages (page 7 line 20 to page 9, line 30; page 10, line 3 to page 12, line 14 and Figure 7). The Examiner has considered this argument and the cited passages, but is not persuaded. The specific passages cited by Applicant appear merely to provide a physical description of the proteins in the most general of terms. Applicant defines regions and domains and the size ranges of each. Applicant fails to teach the significance of these domains in the activities of the proteins, and only discloses that the regions and domains may be found in the protein family. The only

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physical characteristic for which an activity may be assigned is to the signal sequence, which is common to all secreted proteins and not unique to CRSP proteins, and is known to direct secretion. The cited passages of the specification are completely silent with respect to the chemical properties of the proteins or their biological functions. The cited references are nondescript at best with respect to the functions of any CRSP protein family, let alone the activity or activities of CRSP-2. The passage at page 10 to page 12 is especially circular in nature. In almost two pages of text, there is not a single concrete statement as to what any CRSP protein does, much less an indication of the function of CRSP-2. Does it catalyze a reaction? Does it bind DNA? Does it bind proteins? etc. The activities enumerated as 1-6 on page 11 are written in such broad terms, they merely encompass several functions known to be performed by proteins in general. The specification fails to adequately set forth a specific function/activity for these proteins, including CRSP-2, as such there is no specific utility for the claimed proteins/polypeptides.

At best, Applicant has found that CRSP-1 (not claimed) is a secreted factor of unknown function and shares some level of homology with a chicken protein of unknown function, see page 70, line 33. This is the only data presented in the specification. Applicant is encouraged to indicate the experimental data which clearly establishes that a specific, particular function has been determined for CRSP-2. Absent such teachings, none of the utilities asserted by Applicant (for example those at pages 35-39 of the specification) can possibly be regarded as specific and credible.

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Applicant's remarks on the Krupnik et al. reference, found at page 13 of the response have been considered, but again, are not found persuasive, especially in light of the discussion found at page 312 of the Krupnik et al. reference (see also the Office action mailed 13 March 2000, page 6).

Because the specification fails to teach what CRSP-2 does, the claimed invention lacks a specific and credible utility and further, it is unclear how the skilled artisan is to use the protein, for example, as a pharmaceutical (see claim 88, or for what to use a CRSP fusion protein)

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6 (d)). The Group 1600 FAX numbers are (703) 308-4242 or (703) 305-3014. Unofficial faxes may be sent to the examiner at (703) 305-7939. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Remy Yucel, Ph. D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday through Fridays from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Remy Yucel, Ph. D.  
Primary Patent Examiner  
Technology Center 1600  
November 4, 2000